REMARKS

The Office Action of May 25, 2011 has been received and carefully reviewed. It is submitted that, by this Amendment, all bases of rejection and objection are traversed and overcome. Upon entry of this Amendment, claims 1-10, 19-24, and 26-33 are pending in the application. Claims 1-10 and 19-22 have been withdrawn. Claims 11-18 and 25 are cancelled herein. New claims 32 and 33 have been added in order to set forth additional specific embodiments of the Applicant's disclosure. Support for these new claims may be found throughout the application as filed, at least at page 7, lines 13-16 and lines 32-33 and the examples listed on page 10. Reconsideration of the claims is respectfully requested.

In the instant Office Action, the Office notes that Applicant's recitation of "means for substantially accurately dispensing the pharmaceutical solution..." and "...the means for dispensing..." in claims 23 and 25, respectively, has invoked the special claim interpretation provisions of 35 U.S.C. § 112, sixth paragraph. The Applicant points out that claim 23 has been amended to remove the "means for" language and that claim 25 has been cancelled herein. As such, it is submitted that the special claim interpretation provisions of 35 U.S.C. § 112, sixth paragraph are no longer applicable.

Claim 23 stands objected to because the Office considers the phrase "substantially accurately" to be superfluous. While not acquiescing to this objection, the Applicant has removed this phrase from independent claim 23. As such, the instant objection is moot.

Claims 23-31 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the Applicant regards as the invention.

The Office stated that the "means for" language led to ambiguity about which structural components were the means for substantially accurately dispensing. While not acquiescing to the rejection, the Applicant has revised independent claim 23 to recite, in part, "...a pharmaceutical solution to be contained in the fluid reservoir and

to be dispensed from the piezoelectric fluid ejection device or the thermal fluid ejection device, the pharmaceutical solution including an active pharmaceutical ingredient dissolved in a vehicle; wherein the pharmaceutical solution has a viscosity i) ranging from about 1.15 cps to about 1.44 cps, or ii) of 2.6 cps, and a fluid surface tension (a) ranging from about 39 dynes/cm to about 49 dynes/cm, (b) ranging from about 46 dynes/cm to about 54 dynes/cm, or (c) of about 62 dynes/cm; wherein the viscosity and the fluid surface tension are selected so that the pharmaceutical solution is dispensed at a predetermined dosage within a variation of reproducibility of less than about 15%...." Support for the various revisions to claim 23 may be found throughout the application as filed, at least at page 3, lines 11-14, page 5, lines 15-17, page 7, lines 19-22, and page 8, lines 13-19. It is submitted that revised claim 23 is not indefinite.

The Office also states that the terms "substantially highly concentrated" and "substantially low volume" in claim 24 are relative terms that render the claim indefinite. The Office seems to suggest that the terms "highly concentrated" and "picoliter volume" may be more suitable terms. The Applicant has revised claim 24 to recite the suggested terms, as these are supported by the application as filed. In light of these revisions, the Applicant submits that claim 24 is also not indefinite.

For all the reasons stated above, it is submitted that the instant rejection under 35 U.S.C. § 112, second paragraph has been overcome, and withdrawal of the rejection is respectively requested.

Claims 23-25 and 27-31 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Tokie (U.S. Patent No. 6,513,897, referred to herein as "Tokie").

Tokie teaches a fluid dispensing system that may include an inkjet dispenser. Tokie teaches that the controller of his system coordinates the operational control of the inkjet dispenser so as to provide desired deposition of fluid in an accurate and repeatable manner (Col. 11, lines 48-52). Tokie mentions that the fluid dispenser mechanism has its own requirements that "must be met by the fluid material being dispensed in order to ensure reliable and repeatable deposition" (Col. 8, line 66

through Col. 9, line 4). In particular, the fluid material for thermal inkjet printing has a viscosity ranging from 3 cps to 5 cps and the fluid material for piezoelectric inkjet printing has a viscosity ranging from 5 cps to 30 cps (Col. 9, lines 12-16).

In sharp contrast, the Applicant's invention as defined in claim 23 states that the viscosity and fluid surface tension are selected so that the pharmaceutical solution is dispensed at a predetermined dosage within a variation of reproducibility of less than about 15%, where the solution viscosity i) ranges from about 1.15 cps to about 1.44 cps, or ii) is 2.6 cps, and the solution fluid surface tension (a) ranges from about 39 dynes/cm to about 49 dynes/cm, (b) ranges from about 46 dynes/cm to about 54 dynes/cm, or (c) is about 62 dynes/cm.

As acknowledged by the Office, Tokie does not specifically teach the variation of reproducibility defined by the Applicant. The Office argues, however, that it would have been obvious for one to discover optimum workable ranges in Tokie's method.

The Applicant disagrees that it would have been obvious for one to have arrived at the Applicant's invention as defined in claim 23 in view of Tokie. Tokie actually provides suitable viscosity ranges for the solutions dispensed using his device and he indicates that fluids within his viscosity ranges will achieve the desired reproducibility. In light of these teachings, one skilled in the art would be led to utilize fluids *within the viscosity ranges provided by Tokie*, but would **not** be led to alter the viscosity since suitable (presumably optimal) ranges are provided by the reference itself. Furthermore, Tokie does not mention the fluid surface tension as being one of the "requirements that must be met by the fluid" (Col. 8, lines 66-67). It is submitted that one skilled in the art would not be led to optimize a property that is not discussed by the reference.

As stated in the instant application as filed, "the solution including the vehicle and active ingredient have appropriate and predetermined fluidic properties for viscosity ... and surface tension such that ejection from the ejection device is substantially successful and substantially repeatable in subsequent firings." (See page 7, lines 19-22.) The properties of the solution (i.e., the selection of the vehicle

and the pharmaceutical agent) contribute to the reproducibility that is claimed by the Applicant.

Since neither the solution properties nor the variation of reproducibility as defined in the Applicant's claims is taught or suggested by Tokie, it is submitted that the reference fails to render obvious the Applicant's invention as defined in the claims.

For all the reasons stated above, it is submitted that Applicants' invention as defined in independent claim 23, and in those claims depending ultimately therefrom, is not anticipated, taught or rendered obvious by the cited reference, either alone or in combination, and patentably defines over the art of record.

Claims 23-25 and 27-30 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Bernardini, et al. (*Journal of Neuroscience Methods,* 1991, Vol. 38, pages 81-88, referred to herein as "Bernardini").

Bernardini teaches using a piezoelectric fluid jetting device to dispense micro drops of drugs. Bernardini teaches using water as a solvent, which has a viscosity of about 1.00 cps (outside of Applicant's claimed values). Bernardini does not ever mention that reproducibility is related to the properties of the solution, let alone the viscosity and the fluid surface tension of the solution. Without some guidance provided by the reference, one skilled in the art would not be led to include or utilize a pharmaceutical solution whose viscosity and fluid surface tension are selected so that it is dispensed at a predetermined dosage within a variation of reproducibility of less than about 15%. For all the reasons stated above, it is submitted that Applicants' invention as defined in independent claim 23, and in those claims depending ultimately therefrom, is not anticipated, taught or rendered obvious by the cited reference, either alone or in combination, and patentably defines over the art of record.

Claim 26 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Bernardini as applied to claim 25 above, and further in view of Cook et al. (*The*

American Journal of Surgery, 1983, Vol. 146, Issue 6, pages 807-810, referred herein as "Cook").

Claim 26 has been amended herein to depend from independent claim 23 and to include that the vehicle is dimethyl sulfoxide or a mixture of dimethyl sulfoxide and an alcohol. The pharmaceutical solution (i.e., the vehicle and active pharmaceutical ingredient) defined in claim 26 is not taught or suggested by the combination of references. Furthermore, it is submitted that since neither of the references teaches or suggests that reproducibility is related to the properties of the solution, one skilled in the art would not be led to change the vehicle(s) taught by the respective references.

For all the reasons stated above, it is submitted that Applicant's invention as defined in claim 26 is not anticipated, taught or rendered obvious by the cited references, either alone or in combination, and patentably defines over the art of record.

If claim 23 is found to contain allowable subject matter, it is requested that the Examiner also consider claims 1-10 for rejoinder. Claims 1-10 are method of using claims which require all of the limitations of the apparatus as defined in claim 23. Thus, under the requirements of MPEP § 821.04(b), if claim 23 is found to be allowable, it is submitted that claims 1-10 are eligible for rejoinder, and the previous restriction requirement of claims 1-10 should be withdrawn.

It is submitted that the absence of a reply to a specific rejection, issue or comment in the instant Office Action does not signify agreement with or concession of that rejection, issue or comment. Finally, nothing in this amendment should be construed as an intent to concede any issue with regard to any claim, and the amendment of any claim does not signify concession of unpatentability of the claim prior to its amendment.

In summary, claims 1-10, 19-24, and 26-33 are pending in the application. In view of the foregoing arguments, all pending claims are believed to be in condition for allowance, and such action is respectfully requested. Therefore, this response is

believed to be a complete response to the Office Action, and further and favorable consideration is respectfully requested.

If the Examiner believes it would expedite prosecution of the above-identified application, the Examiner is cordially invited to contact the undersigned attorney at the below-listed telephone number.

Respectfully submitted,

DIERKER & ASSOCIATES, P.C.

/Julia Church Dierker/

Julia Church Dierker
Attorney for Applicant
Registration No. 33368
(248) 649-9900, ext. 25
juliad@troypatent.com

3331 West Big Beaver Rd., Suite 109
Troy, Michigan 48084-2813
Dated: August 25, 2011
JCD/JRK/slc